

### **REMARKS**

Claims 20-27 are pending in this application. Claims 20, 23, 26, and 27 are amended. No new matter is added. Reconsideration of the application in view of the foregoing amendments and following comments is respectfully requested.

Claims 20-27 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by U.S. Patent No. 5,989,288 to Pintauro. However, the claims recite features that are neither taught or suggested by Pintauro.

For example, independent claim 20 recites a frame that self-expands radially outward within a bronchial passageway so as to exert a radially-outward force sufficiently to anchor the flow control device against cylindrical walls of the bronchial passageway. Pintauro fails to show a frame that anchors against cylindrical walls of a bronchial passageway. The Pintauro valve assembly is dimensioned such that it cannot anchor against cylindrical walls of a passageway (the urethra) when the valve assembly is in the anchored state. Specifically, the flared anchor 14 of the valve assembly does not and cannot anchor against cylindrical walls of the urethra, but rather has a shape and dimension adapted to anchor against the walls at the base of the bladder, which walls are flared and non-cylindrical, as shown in Figure 5 of Pintauro.

Pintauro makes no mention of the valve assembly anchoring within cylindrical walls of a passageway. Rather, Pintauro teaches away from the valve assembly anchoring within a cylindrical body passageway such as the urethra. This is because the flared anchor is configured to secure the valve assembly relative to the bladder and to prevent the valve assembly from being expelled distally from the bladder into the urethra. This requires that at least a portion of the valve assembly conform to the base of the bladder and be shaped in a flared manner in order to prevent the valve assembly from sliding entirely into the urethra. Such a configuration cannot anchor against cylindrical walls. Furthermore, although Pintauro states that a number of structures can be used to minimize the circumference of the first anchor (column 7, lines 54-56), Pintauro only describes the first anchor in the context of the first anchor protruding into

and conforming to the enlarged dimension of the bladder so as to anchor against a flared wall rather than a cylindrical wall.

In view of the foregoing comments, the rejection of claim 20 should be withdrawn. Claims 21 and 22 are allowable based on their dependence on claim 20 as well as on their own merit.

Independents claim 23 and 27 recite a cylindrically-shaped flow control device, while independent claim 26 recites a cylindrically-shaped seal. Pintauro fails to teach or suggest a cylindrically-shaped flow control device or a cylindrically-shaped seal. As mentioned, Pintauro describes a urethral valve assembly that can be positioned within a patient's urethra and bladder. The valve assembly includes a tubular body 12 that can be located in the urethra, and an anchor 14 that can be positioned adjacent the base of the bladder, as shown, for example, in Figures 1 and 5 of Pintauro. The Pintauro device does not have a cylindrical shape, as it includes an anchor portion with a semiconical shape that inclines generally radially outwardly in the proximal direction from a proximal end of the tubular body. (See Pintauro, column 7, lines 29-32.)

Moreover, Pintauro actually teaches away from the anchor portion of the flow control device having a cylindrical shape, as such a cylindrical shape would not permit the anchor to serve its function, which is to secure the valve assembly relative to the bladder and the urethra. (See Pintauro, column 7, lines 9-11.) In order to properly secure the valve assembly relative to the bladder and prevent the valve assembly from sliding out of the bladder entirely into the urethra, the anchor portion must have a flared, semiconical shape that conforms to the shape of the base of the bladder. (See Pintauro, column 7, lines 7-53.) A cylindrically-shaped anchor would not conform to the shape of the base of the bladder and, therefore, would not prevent the valve assembly from being expelled distally from the bladder into the urethra. Thus, there would not be any motivation to modify the shape of the Pintauro anchor into a cylindrical shape.

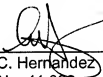
In view of the foregoing comments, applicant respectfully submits that the rejection of claims 203, 26, and 27 should be withdrawn. Claims 24 and 25 are allowable based on their dependence on claim 20 as well as on their own merit.

It is believed that all of the pending claims have been addressed in this paper. However, failure to address a specific rejection, issue or comment, does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above are not intended to be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily.

In view of the above amendments and remarks, all of the claims should be in condition for allowance. A formal notice to that effect is respectfully solicited.

Respectfully submitted,

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